Research Participation & Data Governance Policy

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REACHnet
Research Action for Health Network

I. Overview

A. Purpose: The purpose of this policy is to:

1. Inform investigators how to collaborate with the Research Action for Health Network (REACHnet) in the following capacities:
    - Requesting REACHnet resources and services for their own research initiatives;
    - Representing their health system as the site Investigator in another investigator's research initiatives; and/or
    - Representing the network as the local (i.e., REACHnet) Principal Investigator in a PCORnet study
2. Govern REACHnet's process for determining network and site participation in research projects
3. Govern approvals of data sharing pursuant to the terms of the REACHnet Master Data Sharing and Use Agreement, other applicable Data Sharing and Use Agreements, and IRB requirements

B. Scope: This policy applies to requests by the National Patient-Centered Clinical Research Network (PCORnet) and non-PCORnet Research Partners (institutions involved in the conduct of research as defined at 45 C.F.R. § 64.10 of the HIPAA Regulations and health plans, including REACHnet-affiliated and non-REACHnet-affiliated partners) to conduct research using REACHnet's infrastructure for:

1. Obtaining any data;
2. Conducting observational or interventional studies;
3. Collecting patient-reported/generated data; and/or
4. Accessing stakeholder engagement resources and services.

As set forth below, the research review process for PCORnet requests does not involve all of the steps required for non-PCORnet studies.

C. Decision-making: The REACHnet Coordinating Center facilitates the network's decision-making regarding research participation and the release of clinical and/or research data by working closely with a defined group of health system leaders who represent each of REACHnet's participating health systems, including: Ochsner Health System; Baylor Scott & White Health; Pennington Biomedical Research Center; Tulane University Schools of Medicine and Public Health/Tulane Medical Center [HCA]; LSU Health Sciences Center/University Medical Center New Orleans (LCMC Health); Lallie Kemp Regional Medical Center; and Partnership for Achieving Total Health (PATH) community-based clinics and hospitals). Hereafter, this decision-making body is referred to as "*Partner Health System Leadership*". Members of REACHnet's Partner Health System Leadership are listed in **Appendix A**.

The REACHnet Coordinating Center and Partner Health System Leadership govern the network's research participation and data sharing as follows:

1. First, the REACHnet Coordinating Center performs an administrative review of a given research request, data request, or service request to assess feasibility. Using guidelines approved by Partner Health System Leadership, the REACHnet Coordinating Center conducts this preliminary assessment to determine if the request for services and/or collaboration should be shared with leaders.
2. The REACHnet Coordinating Center communicates about research participation and data sharing opportunities with Partner Health System Leadership on a rolling basis. As research opportunities are shared, each leader acts as a liaison between REACHnet and their partner health system to determine system-level interest in participation and, if applicable, recruit system-level investigators and sites.

Decision-making for research participation is further discussed in the *Requesting Research Services* sections of this policy (sections II and III). Decision-making for the release of data is discussed in the *Data Governance* section of this policy (section V).

II. Requesting Research Services – Process for Investigators

A. Submission Procedures

Investigators who are interested in leveraging REACHnet resources and/or services are invited to submit the appropriate REACHnet Service Request Form(s) via REACHnet's online submission portal, Eco (https://eco.reachnet.org). Using Eco, investigators are able to organize all request-related forms in one project space and track the status of requests. REACHnet may also correspond with investigators via phone or email to discuss content of an application form before the form(s) is formally reviewed.

Investigators can find submission forms and information about REACHnet services on REACHnet's website (http://www.reachnet.org/resources/forms/). Forms applicable to the research participation process include:

- *Prospective Research Request Form* (see Sections II.B. and V.A.)
- *Data Request Form* (i.e., for retrospective research; see Sections II.C. and V.B.)
- *Prep-to-research Query Request Form* (see Section V.C.)
- *Request for Engagement Services* (see Section VI)

Details for completing each form are described below.

B. Prospective Research Requests

Investigators who wish to access REACHnet services are invited to submit an application addressing the following components of their proposed research project:

1. Specific Aims / Research Questions
2. Target population
3. Description of intervention(s) and comparison groups or study cohort
4. Data needs, including clinical and patient-reported data collected by REACHnet
5. Proposed research sites (health systems), if applicable
6. Research team (by name and institution)
7. Funding details, if applicable
8. Use of REACHnet resources/services (note: services will require appropriate budget allotments)
9. Engagement Plan detailing how patients, clinicians, and other stakeholders (as applicable) will be engaged in the protocol development and project execution
10. Use of other CDRN or PPRN resources/services
    - Investigators who are interested in engaging other PCORnet Patient Powered Research Networks (PPRNs) or Clinical Data Research Networks (CDRNs) to collaborate on a study are encouraged to communicate with the REACHnet Coordinating Center about their research ideas and potential PCORnet collaboration
    - If deemed feasible, the REACHnet Coordinating Center will advise investigators through the additional application procedures through the PCORnet Front Door
    - The use of other CDRN or PPRNs for research purposes will require additional regulatory documentation beyond that required for REACHnet

The *REACHnet Prospective Research Request Form* reflects the above requirements. The request must be submitted, reviewed, and approved prior to receiving a letter of support from REACHnet for a funding application**. Please allow at least 30 days for the review process.**

C. Retrospective Research Requests (i.e., data-only requests)

Investigators who wish to obtain a single flat file of REACHnet partner data are invited to submit a *Data Request Form* addressing the following components of their proposed research project:

1. Specific Aims / Research Questions
2. Description of population of interest, including query parameters for inclusion/exclusion criteria
3. Engagement Plan detailing how patients, clinicians, and other stakeholders (as applicable) have been or will be engaged in generating the project idea or interpreting the results
4. Data needs, including specific clinical and patient-reported data elements collected by REACHnet
5. Funding details, if applicable
6. Use of other CDRN or PPRN resources/services
    - Investigators who are interested in engaging other PCORnet Patient Powered Research Networks (PPRNs) or Clinical Data Research Networks (CDRNs) to collaborate on a study are encouraged to communicate with the REACHnet Coordinating Center about their research ideas and potential PCORnet collaboration
    - If deemed feasible, the REACHnet Coordinating Center will advise investigators through the additional application procedures that are outlined in the PCORnet Front Door Policy
    - The use of other CDRN or PPRNs for research purposes will require additional regulatory documentation beyond that required for REACHnet

D. Review Process, Partner Health System Participation, and Communication of Decision

1. The investigator will receive an email notification through Eco that the status of their project is “under review” or “needs action” within 10 working days of submission. The REACHnet Coordinating Center may communicate with the investigator during this time to clarify data needs and requested services. If necessary, the investigator will be responsible for revising the request form during this time.
2. The REACHnet Coordinating Center will review the submitted form and determine whether fulfilling the request is feasible.
3. If deemed feasible, the REACHnet Coordinating Center will present the opportunity to REACHnet Partner Health System Leadership, and leaders will determine whether their respective health system is interested in participating. Leaders will identify co-investigators and sites from their respective health systems for interventional studies or determine if their respective health system will contribute requested data in response to data-only requests or prospective observational studies (for which co-investigators may also be recruited).
4. In response to both prospective and data-only research opportunities, the REACHnet Coordinating Center must receive express written consent to participate via email from Partner Health System Leadership.
5. The REACHnet Coordinating Center will communicate a final decision about collaboraton through Eco within 30 working days after the Eco project was changed to “under review”. If the research request is approved, REACHnet will inform the investigator of the decision by changing the status of the Eco project to “approved”. If collaboration is deemed unfeasible during the formal review process, the Eco project status will be changed to ”rejected”. Investigators are invited to resubmit requests or contact the REACHnet Coordinating Center directly with questions about this decision.

III. Requesting Research Services – Process for PCORnet Research Opportunities

A. Opportunities to participate in studies initiated through PCORnet will be managed by the REACHnet Coordinating Center.
B. The REACHnet Coordinating Center will determine whether the research opportunity is feasible.
C. If deemed feasible, the REACHnet Coordinating Center will present the opportunity to the Partner Health System Leadership, and leaders will determine whether their respective health system is interested in participating. Leaders will identify co-investigators and sites from their respective health systems for interventional studies or determine if their respective health system will contribute requested data in response to data-only requests or prospective observational studies (for which co-investigators may also be recruited).
D. In response to both prospective and data-only research opportunities, the REACHnet Coordinating Center must receive express written consent to participate via email from Partner Health System Leaders.
E. The REACHnet Coordinating Center will communicate with PCORnet about whether the network (i.e., some combination of component health systems, but not necessarily all) will participate in a proposed study, based on the systems' willingness to participate.

IV. Regulatory Requirements

All approved research requests are subject to:

A. Applicable IRB approval requirements based on the type of study (see Table 2 for more information);
B. The terms of the REACHnet Master Data Sharing and Use Agreement, which sets forth any additional Data Sharing and Use Agreements that must be executed before data is shared; and
C. Partner Health System Leader approval for data sharing as set forth in the *Data Governance* section below.

V. Data Governance

REACHnet partner data is available to investigators to support prospective and data-only research projects. In addition, REACHnet partner data can support research preparation projects through prep-to-research queries and administrative queries geared toward ensuring data quality and readiness. Data governance differs based on the type of data requested. Data type definitions are aligned with those specified in the REACHnet Master Data Sharing and Use Agreement and PCORnet Data Sharing Agreement (DSA). They include:

1. Type 1: Administrative Queries (e.g., PCORnet Data Characterization)
2. Type 2: Analytic queries requiring return of de-identified aggregate data
3. Type 3: Analytic queries requiring return of de-identified individual level data
4. Type 4: Analytic queries requiring return of a limited data set (CDM[1] or CDM+[2])
5. Type 5: Analytic queries requiring return of identifiable individual level data

[1] The PCORnet Common Data Model (CDM) is a way of organizing clinical health data into a standard structure. Each PCORnet partner network maps data to the same consistent format (i.e., with the same variable name, attributes, and other metadata). For more information, visit http://www.pcornet.org/pcornet-common-data-model/.
[2] REACHnet has the capacity to assist investigators in acquiring data outside of the CDM from REACHnet partner health systems for research purposes.

REACHnet references these five data types throughout the *Data Governance* section of this policy. The sections below describe regulatory and administrative approval requirements for sharing the data types listed above. Table 1 provides an overview of these requirements.

A. Data to support prospective research

Data to support prospective research will take the form of data types 2-5. To receive data for prospective research projects, the researcher must complete the steps described in the *Requesting Research Services* and *Regulatory Requirements* sections of this policy.

1. No data, regardless of type, will be released without Partner Health System Leader participation approval, as set forth in the *Requesting Research Services* sections (II and III) above and fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section (IV) above.
2. Once Partner Health System Leadership approves participation and applicable regulatory requirements are met, data types 2-5 can be released without additional review and/or approval from participating Partner Health Systems Leadership.
3. Ongoing releases of data types 2-5 can occur without additional approval from participating Partner Health System Leadership.
4. Additional data requests beyond those expressely defined in the applicable IRB, REACHnet Master Data Sharing and Use Agreement, and additional Data Sharing and Use Agreements, if applicable, will need to be assessed and regulatory requirements implemented before data sharing can occur.
5. All data transfer will occur in a secure capacity.

B. Data to support retrospective research

Data to support retrospective research typically take the form of data types 3 and 4 (but could also include types 2 and 5). To receive data for retrospective research projects, the researcher must complete the steps described in the *Requesting Research Services* and *Regulatory Requirements* sections of this policy.

1. No data, regardless of type, will be released without Partner Health System Leader participation approval, as set forth in the *Requesting Research Services* sections (II and III) above and fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section IV above.
2. Once Partner Health System Leadership approves participation and applicable regulatory requirements are met, data types 2-5 can be released without additional review and/or approval from participating Partner Health System Leadership.
3. Additional data requests beyond those expressely defined in the applicable IRB, REACHnet Master Data Sharing and Use Agreement, and additional Data Sharing and Use Agreements, if applicable, will need to be assessed and regulatory requirements implemented before data sharing can occur.
4. All data transfer will occur in a secure capacity.

C. Data to inform future research

Data to inform future research takes the form of a prep-to-research (PTR) or prep-to-analysis (PTA) query. Prep-to-research/analysis queries are data type 2. Prep-to-research queries assess the number of eligible patients meeting defined inclusion/exclusion criteria, while prep-to-analysis queries assess the frequency of outcomes among defined patient groups. Query requests are received locally via Eco as *Query Request Forms*. REACHnet also receives prep-to-research queries through the PCORnet Distributed Research Network.

1. Approval from Partner Health System Leadership is not required prior to running a prep-to-research query, but pre-approval from Partner Health System Leadership is required prior to running a prep-to-analysis query.
2. No data, regardless of type, will be released without fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section IV above.
3. Once prep-to-research/analysis queries are complete, results are sent to respective Partner Health System Leadership via email or through the REACHnet Query Tracking System. For prep-to-research queries, the Partner Health System Leadership is allowed 72 hours (3 business days) to review their health system specific results from each prep-to-research query and respond if they wish to opt out of sharing results with the requester. Active approval is not required to share results with the requester. For prep-to-analysis queries, approval from Partner Health System Leadership obtained with written consent via email or within the Query Tracking System is required to release results to the requester.
4. Prep-to-analysis query results cannot be released to requesting investigators without the approval of the Partner Health System Leadership.

To protect patient privacy, REACHnet does not release query results where the cell count is between 1-10. If query results are between this range, they are marked as "LE 11" or "below threshold (BT)."

D. Data to inform *potential* future research

Data to inform potential future research takes the form of a pre-prep-to-research query. Pre-prep-to-research queries are a data type 2; however, pre-prep-to-research queries only release aggregate results for all of REACHnet and do not provide system-specific results.

1. No data, regardless of type, will be released without fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section IV above.
2. Approval from Partner Health Systems Leadership is not required prior to running a pre-prep-to-research query or releasing the results to the requester.

To protect patient privacy, REACHnet does not release query results where the cell count is between 1-10. If query results are between this range, they are marked as "LE 11" or "below threshold (BT)."

E. Data for administrative purposes

Data for administrative purposes are defined as data type 1.

1. No data, regardless of type, will be released without fulfillment of applicable regulatory requirements as summarized in the Regulatory Requirements section IV above.
2. Approval from participating health systems is not required prior to running data type 1 queries.
3. Once results of administrative queries are ready, they are sent to respective Partner Health System Leadership via email or through the REACHnet Query Tracking System. The Partner Health System Leadership is required to review and approve their health system-specific results from each administrative query. Approval is obtained with written consent via email or by indicating their approval within the Query Tracking System.
4. Administrative or data type 1 results cannot be released to PCORnet without the approval of the participating health system.

Table 1: Partner Health System Leadership Approval Requirements for Data Types

CATEGORY	REACHnet & PCORnet DSA data types	APPROVAL REQUIREMENT (for partner health system participation)	APPROVAL REQUIREMENT (before data release)
Prospective studies (e.g.,ongoing study with multiple data deliverables)	Types 2-5	Approval to participate must be sent to REACHnet Coordinating Center via email	No approval necessary before data release
Retrospective studies (e.g., data-only request associated with one single data deliverable)	Types 2-5	Approval to participate must be sent to REACHnet Coordinating Center via email	No approval necessary before data release
PTR queries (e.g., not yet associated with an active or proposed study)	Type 2	Approval is NOT required prior to query run	Approval is NOT required prior to releasing results (72 hours/3 business days allowed for review and opt-out)
PTA queries (e.g., not yet associated with an active or proposed study)	Type 2	Approval required prior to query run	Approval is required prior to releasing results
Pre-PTR queries	Type 2	Approval is NOT required prior to query run	Approval is NOT required prior to releasing results
Administrative queries	Type 1	Approval is NOT required prior to query run	Approval is required prior to releasing results

VI. Engagement Services

Engaging patients, clinicians, and community stakeholders during this initial stage of proposal development follows PCORI's suggested steps for engaging stakeholders throughout the entire research process. (More information about stakeholder engagement can be found in PCORI's Engagement Rubric.)

To help support investigators with project-specific engagement needs, REACHnet has developed an engagement infrastructure that includes services such as consultation on engagement plan development and resources such as access to REACHnet's *Health in Our Hands* patient network. Investigators who are interested in collaborating with REACHnet to fulfill their engagement needs are encouraged to submit a *Request for Engagement Services* form.

NOTE: Investigators who are requesting engagement services *in addition to other REACHnet services* as a component of prospective research do not need to complete a separate *Request for Engagement Services* form. Instead, this request should be detailed in the section entitled "Stakeholder Engagement Services" of the *Prospective Research Request* form.

Given that many funding opportunities now require that proposals outline plans for engagement of patients and other stakeholders, (e.g. caretakers, community members, clinicians, etc.), it is strongly recommended that investigators complete this form *several months prior* to preparing their proposal.

A. Requirements for Engagement Services Requests

Investigators who wish to access REACHnet engagement services are invited to submit a request addressing the following components of their proposed research project:

1. Purpose of engagement within the project
2. Description of condition or community of interest
3. Description of project's engagement needs and goals
4. Description of research team's current resources and level of experience with engagement in research
5. Selection of specific REACHnet engagement services/resources
6. Engagement requirements set forth by funder, if applicable

B. Review Process & Communication of Decision

Requests for Engagement Services will be reviewed by the REACHnet Coordinating Center's engagement personnel. Within 5 working days after the request is submitted via Eco, the investigator will receive an email notification that their project is "under review". If the engagement request is deemed feasible by the REACHnet Coordinating Center, the investigator will receive an email notification that their project is "approved". At this time, REACHnet engagement personnel will communicate directly with the investigator via Eco, phone, or email to more thoroughly discuss the investigator's request and collaborate on the development of next steps.

VII. IRB Requirements

REACHnet-initiated projects are required to follow REACHnet's streamlined IRB review process, which entails a shared or ceded review model among REACHnet partners. REACHnet partner health system IRBs are members of two national platforms that facilitate shared and ceded reviews: (1) IRBchoice (https://www.irbchoice.org/p/) and (2) SMART IRB (https://smartirb.org/).

Prior to IRB submission, investigators are encouraged to contact REACHnet personnel for guidance on IRB procedures using one of the two shared review platforms. PCORnet-designated and NIH-funded studies are required to use SMART IRB. All other studies may use SMART IRB (if applicable) or IRBchoice.

The IRB processes for various research scenarios are summarized in Table 2.

Table 2: IRB Process Guidance by Research Scenario

Research Design	Partnership Framework	IRB Framework
Deidentified data Observational No individual patient consent	Co-investigators at each data contributing institution	Lead IRB identified; ceded or shared review by all data contributing institutions using IRB choice or SMART IRB
	Some data contributing institutions do not have an investigator engaged in the research	Lead IRB identified; ceded or shared review by data contributing institutions with investigators engaged using IRB choice or SMART IRB; *IRBs for data contributing institutions without investigators engaged in the research do not require review*
Limited dataset Observational No individual patient consent	Co-investigators at each data contributing institution	Lead IRB identified; ceded or shared review by all data contributing institutions using IRB choice or SMART IRB

	Some data contributing institutions do not have an investigator engaged in the research	Lead IRB identified; ceded or shared review by data contributing institutions with investigators engaged using IRB choice or SMART IRB; IRBs for data contributing institutions without investigators engaged in the research will be asked for a determination on whether or not the study constitutes human subjects research and requires review
Health in Our Hands and/or survey data collection Prospective Patient recruitment/consent	Co-investigators at each participating institution	Lead IRB identified; ceded or shared review by all participating institutions using IRB choice or SMART IRB
Interventional trial Prospective Patient recruitment/consent	Co-investigators at each participating institution	Lead IRB identified; ceded or shared review by all participating institutions using IRB choice or SMART IRB

VIII. Reporting Requirements

At the conclusion of the study, research findings must be reported to REACHnet. It is recommended that investigators assist in the summary and dissemination of results in a patient-friendly format, including through the Health in Our Hands patient network and on the REACHnet website.

Investigators are required to notify REACHnet of any manuscripts accepted for publication and abstracts or papers accepted for presentation within 15 days of acceptance. Authors/presenters are required to formally acknowledge REACHnet in all publications and presentations of research conducted using the network.

Please refer to REACHnet's Dissemination Policy for all manuscripts and conference presentations derived from research conducted via REACHnet.

1. **Acknowledgments section of manuscript or report:**
    a. It is recommended that the following language be included in the Acknowledgements Section of the manuscript or report to properly acknowledging collaboration with REACHnet: *"Supported in part by CDRN 1306-04864 from the Patient Centered Outcomes Research Institute. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Research Action for Health Network (REACHnet), Patient Centered Outcomes Research Network (PCORnet), or Patient Centered Outcomes Research Institute (PCORI)."*
    b. In addition to a funding acknowledgement, the following standardized acknowledgement of the REACHnet partnership will be used for ALL publications, presentations, and other dissemination-related activities, regardless of the authors listed: "*The authors acknowledge the participation of REACHnet partner health systems: [name all participating health systems] in this project.*

2. **Citing a prep-to-research query or analysis using data from REACHnet's CDM Data Warehouse:** Investigators are required to cite all results acquired from REACHnet partner data that are presented in any format. The following language is recommended for citing prep-to-research or analysis results using data from REACHnet's CDM Data Warehouse: Research Action for Health Network, Louisiana Public Health Institute. Date dataset was created or updated. *Title or brief description of dataset, including time period, target patient population and health system(s) covered in the data if applicable* [Data file/Prep-to-research query]. New Orleans, Louisiana: Louisiana Public Health Institute.

Appendix A: REACHnet Partner Health System Leadership

As mentioned throughout this policy, REACHnet's decision-making is primarily governed by a group of health systems leaders from REACHnet's partner health systems (i.e., data contributors) and institutions. The appointees' decision-making responsibilities vary by health system/institution depending on the extent of the system's data contribution. The table below lists the representatives from each partner health system/institution who are responsible for system or clinic-level decision-making for REACHnet.

REACHnet Decision-Making: Partner Health System Leadership	
Ochsner Health System	**Eboni Price-Haywood, MD, MPH, FACP** *Director, Center for Applied Health Service Research* Ochsner Health System
Baylor, Scott & White Health	**Andrew Masica, MD, MSCI** *Vice President, Chief Clinical Effectiveness Officer* Baylor Scott & White Health
Pennington Biomedical Research Center (PBRC) NOTE: PBRC does not house clinical data and is therefore only responsible for sharing research opportunities with institutional investigators.	**Peter Katzmarzyk, PhD, FACSM, FAHA** *Associate Executive Director for Population and Public Health Sciences, Marie Edana Corcoran Endowed Chair in Pediatric Obesity and Diabetes* Pennington Biomedical Research Center
Louisiana State University Health Care Services Division (LSU HCSD), Lallie Kemp Regional Medical Center	**John Couk, MD** *Chief Medical Officer* Louisiana State University Health Care Services Division
Tulane University Schools of Medicine and Public Health/Tulane Medical Center (HCA)	**Vivian Fonseca, MD, FRCP** *Tullis-Tulane Alumni Chair in Diabetes, Professor of Medicine, Chief – Section of Endocrinology* Tulane University School of Medicine
Partnership for Achieving Total Health (PATH)/Greater New Orleans Health Information Exchange (GNOHIE) NOTE: Approval for release of query results is given by the Executive Director, whereas approval to participate in prospective research is solicited at the clinic level.	**Clayton Williams, MBA** *Director of Clinical Transformation, Executive Director of PATH* Louisiana Public Health Institute
LSU Health Sciences Center/University Medical Center New Orleans (LCMC Health)	**Jyotsna Fuloria, MD** *Vice President of Clinical Research* University Medical Center New Orleans